IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

UNITED STATES OF AMERICA et al., EX REL. SCARLETT LUTZ and KAYLA WEBSTER,

Plaintiffs/Relators,

v.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Defendant.

C/A No. 9:14-cv-3699-RMG

ORAL ARGUMENT REQUESTED

RELATORS' SUR-REPLY OPPOSING LABORATORY CORPORATION OF AMERICA HOLDINGS' MOTION TO DISMISS

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I. ARGUMENT

A. LabCorp Contradicts the Settled Principle that a Laboratory's Conduct that Leads to Medically Unnecessary Tests Can Support FCA Liability.

LabCorp seeks to avoid liability for actively encouraging medically unnecessary tests by (1) taking this Court's remarks out of context; and (2) inadequately distinguishing cases cited by Relators in support of FCA liability.

First, LabCorp misconstrues this Court's statement during the trial of BlueWave, Floyd Calhoun Dent III, Robert Bradford Johnson, and Latonya Mallory. *See* Reply p. 2. LabCorp highlights the Court's comment that "[y]ou cannot hold a lab liable" on a theory under which "the lab[] had to second-guess the doctors." However, LabCorp omits the remainder of the discussion in which this Court drew a distinction between a lab second-guessing a physician's order (which is not grounds for FCA liability) and a lab that was "pushing [] unnecessary tests" (which is grounds for FCA liability, and what Relators allege here). Trial Tr. 2710:1–6; *see also* Trial Tr. 2707 ("[I]f they did what you claim they did, there is a scheme to engage and to order unnecessary tests."). As this Court recognized, a lab may be held liable for encouraging submission of medically unnecessary testing. In short, this Court endorsed the precise legal principle Relators invoke.

Second, without providing contrary authority (other than a misrepresentation of this Court's own statements), LabCorp unsuccessfully attempts to distinguish the cases Relators' rely on (*Groat*, *Berkeley*, and *Downy*). LabCorp never addressed the underlying principal of Relators' cases—namely, that labs whose conduct encourages medically unnecessary testing can be held liable under the FCA. *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 165 (D.D.C. 2017); *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 497–99 (D.S.C. 2016); *United States ex rel. Downy v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1172

(D.N.M. 2000).

LabCorp tacitly acknowledges FCA liability for encouraging unnecessary testing, but attempts to narrow the operative rule. Without justification, LabCorp mints a so-called "direct" (versus "indirect") encouragement standard for FCA liability for medically unnecessary testing. LabCorp then characterizes the three factual scenarios in *Groat*, *Downy*, and *Berkeley* as "direct" encouragement, but concludes that Relators' allegations fall into LabCorp's newly-created "indirect" encouragement category. Of course, LabCorp offers no legal support for its "direct" versus "indirect" encouragement distinction, nor can it. The FCA is a broad-based statute seeking to prevent all kinds of fraud on the Government and should not be read so narrowly. *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968). Further, because Relators have alleged that LabCorp both submitted and *caused* the submission of false claims; it matters not whether LabCorp's conduct was direct or indirect. *See United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 41 n. 9 ("Section 3729(a)(1)(A) imposes liability on defendants who directly 'present[] a false or fraudulent claim for payment or approval,' and defendants who indirectly 'cause[] to be presented[] a false or fraudulent claim for payment or approval.'"). LabCorp's novel theory is baseless.[1]

[1] Even under LabCorp's unfounded construct of requiring "direct" encouragement, Relators' allegations are sufficient. In *Downy*, the complaint sufficiently alleged encouragement where defendants "combined [two] tests . . . on their order forms . . . and provid[ed] misleading information concerning the necessity" of the tests. 118 F. Supp. 2d at 1163. Likewise, in *Groat*, the complaint sufficiently alleged encouragement where it used "pre-printed test requisition forms" and "false marketing statements" to encourage testing. 296 F. Supp. 3d at 165. In other words, both *Groat* and *Downy* included: (1) the use of a prepared requisition form; and (2) some additional encouragement (what LabCorp apparently construes as "direct" encouragement). Here, Relators' FAC alleges that LabCorp encouraged physicians to order medically unnecessary testing through: (1) a requisition form with a space marked "other" where a physician would write in "HDL/Singulex" (FAC ¶¶ 364–65); and (2) encouraging unnecessary testing by telling physicians that LabCorp would not provide free phlebotomy services for HDL or Singulex referrals unless the physician also referred a test to LabCorp. FAC ¶ 332 (describing policy); ¶ 353 (LabCorp

B. LabCorp's Reply Does Not Justify Dismissal of Relators' Two State-Law Claims for Violations of Statutes Prohibiting Fraud Against Private Insurers.

(i) LabCorp's novel standing argument is rife with misstatements.

Most egregiously, LabCorp claims that "California declined to intervene" in this lawsuit. Reply p. 14. The relevant agency under CIFPA, as LabCorp well knows, is the California Department of Insurance ("CDI"), and not the State of California. The Court granted Relators' motion to dismiss all of its claims arising under state False Claims Acts, including California's, on June 21, 2018, five days before Relators filed the operative complaint. Dkt. No. 47. Relators' CIFPA claim is its only remaining claim arising under California law.

In its statement of interest, the CDI reported to the Court that it "has yet to make its intervention decision." Dkt. No. 63-1 at 2. Indeed, as LabCorp is well aware, the CDI has been actively investigating Relators' allegations and has requested documents and interviews from LabCorp. For LabCorp to suggest that "California declined to intervene" in Relators' lone California-law claim is simply incorrect.

Also incorrect is LabCorp's claim that both Relators and the CDI have failed to address the meaning of "interested persons" under CIFPA and ILCFPA. Reply pp. 12–13. Relators and the CDI have explained that a relator's "interest" under CIFPA and ILCFPA refers to her status as the original source of allegations not previously disclosed in another proceeding or by the media.

And the California agency charged with enforcing CIFPA supports Relators' interpretation. Under California law, courts must "tak[e] into account and respect[]" the meaning

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informed Dr. Miller that it "was willing to continue to provide Dr. Miller with free blood draw and processing services for referrals to HDL and Singulex as long as Defendant LabCorp received referrals from Dr. Miller[.]"). Relators also alleged that, at times, the referrals sought by LabCorp were duplicative of a test that was already in the HDL or Singulex panel and that as the party drawing all of the blood samples and recording the same, LabCorp knew when medically unnecessary tests were referred to LabCorp. FAC ¶¶ 5, 361–68, 529.

ascribed to a statute by the agency charged with implementing its provisions. *Yamaha Corp. of America v. State Bd. of Equalization*, 960 P.2d 1031, 1034 (Cal. 1998). While an agency's interpretation is not binding, it may be "helpful, enlightening, even convincing . . . ." *Id.* (citation omitted). Here, the interpretation endorsed by the CDI, as articulated in one of the first statements of interest it has filed in litigation, simply reflects the purpose of *qui tam* statutes: to empower private attorney generals to redress the injuries suffered by the true parties in interest – here, the very private insurers that LabCorp and its co-conspirators defrauded.

(ii) To bolster its Rule 9(b) argument, LabCorp misinterprets Nathan.

LabCorp's argument that Relators' CIFPA and ILCFPA claims do not pass muster under Rule 9(b) rests on a misreading of *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), a case that it cites for the first time in its reply brief. *Nathan* does not, as LabCorp implies, require that particularized allegations of specific false claims be presented to insurers in California and Illinois. Instead, *Nathan* recognizes that "specific allegations of the defendant's fraudulent conduct" can lead to the "plausible inference that false claims were presented." *Id.* at 457. In that manner, *Nathan* is no different than the "three district-court decisions from other circuits" Relators cite and that LabCorp wrongly claims "follow a more relaxed view of Rule 9(b)." Reply p. 15. All four cases – *Nathan*, *Spay*, *Pogue*, and *Drennen* – make clear that courts should evaluate on a case-by-case basis whether the allegations of nationwide fraud lead to a "plausible inference" of presentment. *Nathan*, 707 F.3d at 457. As stated in their response, Relators' FAC is replete with such allegations. Response pp. 28–30.

LabCorp's position that Relators' allegations under the CIFPA and ILCFPA do not satisfy Rule 9(b) is belied by LabCorp's failure to seek dismissal of Count I of Relators' FAC (alleging LabCorp presented or caused to be presented false claims tainted by kickbacks to government health care programs, in violation of the federal FCA, which includes claims for government

beneficiaries in California and Illinois). That unchallenged claim is rooted in an anti-kickback theory, as are Relators' CIFPA and ILCFPA claims. LabCorp has failed to explain why Relators' federal FCA claim (for referrals of beneficiaries covered by government healthcare programs) meets Rule 9(b), but their CIFPA and ILCFPA claims (which relate to referrals of patients covered by private insurance) do not.[2] There is no explanation for the discrepancy, except LabCorp's desire to escape liability for claims submitted to private insurers.

C. LabCorp's Reply Does Not Undermine the Adequacy of Relators' Allegations of Conspiracy to Violate the FAC.

LabCorp's Reply incorrectly contends that "Relators do not (and cannot) identify any particularized allegations about an unlawful agreement between LabCorp, HDL, and Singulex." Reply p. 13. This argument fails because the established FCA case law states that: (1) an agreement may be inferred from allegations of underlying conduct; and (2) the cases cited by LabCorp do not suggest otherwise.

First, the agreement in a FCA conspiracy may be reasonably inferred at the motion to dismiss stage from allegations of the co-conspirators' underlying conduct. *See* Response pp. 27–28; *see also United States ex rel. Tran v. Computer Sciences Corp.*, 53 F. Supp. 3d 104, 134 (D.D.C. 2014) ("[I]t is well-established that a plaintiff need not allege than an express or formal agreement was entered into in order to establish that the parties were in agreement for the purpose of a conspiracy claim."); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193–94 (5th Cir. 2009) (holding relator adequately alleged a conspiracy through detailed allegations of a meeting and specific topics discussed at the meeting from which a reasonable jury could infer that the conspirators were in agreement to create false records); *United States v. Toyobo Co. Ltd.*, 811

[2] In many cases, the same physician, including those practicing in California and Illinois, referred patients insured by government health care programs and privately insured patients to LabCorp and HDL or Singulex.

F. Supp. 2d 37, 51 (D.D.C. 2011) (holding that "detailed allegations about the meetings [between certain alleged coconspirators] fulfills the requirements for an FCA conspiracy claim under Rule 9(b) at the motion to dismiss stage in the litigation.");[3] *United States ex rel. Westrick v. Second Chance Body Armor, Inc.*, 685 F. Supp. 2d 129, 141 (D.D.C. 2010) (holding that "detailed assertion about the meetings between [alleged co-conspirators] fulfills the requirements for a conspiracy claim under § [3729(a)(1)(C)] at the motion to dismiss stage in the litigation."); *United States ex rel. Wilkins v. N. Am. Const. Corp.*, 173 F. Supp. 2d 601, 640–41 (S.D. Tex. 2001) ("The government has also sufficiently alleged circumstances that could lead to a reasonable inference that there was an agreement among defendants . . . to defraud the government by submitting a false or fraudulent claim.") *overruled on other grounds*, 575 F.3d 458, 469 (5th Cir. 2009).

Second, LabCorp's Reply cites several cases to argue that Relators' FAC fails to sufficiently allege an agreement. However, in each case, LabCorp cites the complaint lacked particular allegations of underlying conduct from which the court could infer an agreement; and none support the proposition that it is improper at the motion to dismiss stage to infer a conspiratorial agreement from LabCorp's conduct. For example, in *United States ex rel. Westfall v. Axiom Worldwide, Inc.*, the court noted the lack of allegations regarding "particular communication[s] between or among the alleged co-conspirators that demonstrates an[]

[3] Notably, LabCorp's Reply cites a separate holding from *Toyobo* to suggest that allegations of meetings between alleged co-conspirators cannot support an inference of an agreement. *See* Reply p. 13 (citing *Toyobo*, 811 F. Supp. 2d at 50-51). In *Toyobo*, the allegations of two meetings in two paragraphs of the complaint were insufficient to support an inference of an agreement between the defendant and body armor manufacturers. *Id.* at 50–51. However, more detailed allegations of meetings between the defendant and weavers of fabric used by the body armor manufacturers were sufficient to survive at the motion to dismiss stage. *Id.* at 51. Here, Relators' detailed allegations of meetings between LabCorp, HDL, and Singulex, occurring while LabCorp was actively participating in the conspiracy, are sufficient to support a strong inference of a conspiratorial agreement.

agreement" or "where or when the agreement was reached." 2009 WL 1424213 at *6 (M.D. Fla. May 20, 2009). Similarly, the complaints at issue in *United States ex rel. Dekort v. Integrated Coast Guard Systems* and *United States ex rel. Capella v. Norden Systems, Inc.*, did not include allegations of underlying conduct from which an agreement among co-conspirators could be inferred. *See Dekort*, 705 F. Supp. 2d 519, 548 (N.D. Tex. 2010); *Capella*, 2000 WL 1336487 at *11 (D. Conn. Aug. 24, 2000).

Here, the facts alleged in the FAC support the logical inference that LabCorp agreed to participate in the conspiracy by drawing blood for HDL and Singulex, and did so in exchange for other referrals of LabCorp testing. *See* Response pp. 27–30.

- Contrary to LabCorp's assertion, Relators' FAC identifies the "who" of the conspiratorial agreement by identifying the specific executives involved in reaching the conspiratorial agreement. *See* Response pp. 30-31; FAC ¶¶ 381–82 (identifying David King, LabCorp's CEO, Ben Miller, LabCorp's EVP of Business Development, and Anil Asnani, VP of Strategic Planning and Corporate Development); ¶ 397 (identifying Miller and Eric Lindblom, SVP of Esoteric Business and Specialty Sales).

- Likewise, Relators' FAC identifies "when" the agreement was entered and ended. FAC ¶ 388 (LabCorp pursued business relationships with Singulex and HDL since at least the end of 2010); ¶ 332 (by early 2011, LabCorp started policy of *quid pro quo* draw for HDL and Singulex as long as a referral was also being made to LabCorp); ¶¶ 381–82 (explored further opportunities for collaboration including February 2013 discussion of a "strategic partnership"); ¶ 389 (in mid-2011 LabCorp meets HDL to discuss collaboration with or outright purchase of HDL); ¶¶ 439, 443 (Since at least July 2012, LabCorp was being paid to perform tests for Singulex, including tests that were part of the Singulex panels tied to physician kickbacks); ¶ 395 (February 2013, HDL and LabCorp entered a formal non-disclosure agreement and exchanged cell phone numbers); ¶ 397 (March 1, 2013 meeting where LabCorp and HDL confirmed the "mutually beneficial" use of LabCorp's "Patient Service Centers – phlebotomists."); ¶ 422 (LabCorp terminated the agreement with HDL on July 28, 2014).

Throughout the time when these meetings took place, from 2010 through 2014, LabCorp was already actively participating in the conspiracy with HDL and Singulex by providing blood samples needed for its physician customers to receive kickbacks from HDL and Singulex. *See, e.g.* FAC ¶¶ 2, 15, 18, 529. Viewed together with the other allegations in the FAC, these facts

support an inference of an agreement between LabCorp, HDL, and Singulex.

II. CONCLUSION

Relators respectfully request the Court deny LabCorp's Motion in its entirety, or, in the alternative, grant Relators' leave to amend.

This the 29th day of November, 2018.

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